FDA U.S. FOOD & DRUG ADMINISTRATION

Sept 24, 2019

Ed Cara
MuckRock News, DEPT MR 77587
411A Highland Ave
Somerville, MA 02144

In reply refer to file: F19-6320

Dear Mr. Cara,

This is in reply to your Freedom of Information Act (FOIA) request dated July 18, 2019, in which you requested "the adverse event report, or similar documentation of a patient death associated with investigational fecal microbiota for transplantation or FMT, as detailed here: https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/important-safety-alert-regarding-use-fecal-microbiota-transplantation-and-risk-serious-adverse . Any adverse event reports of patient infections by a multi-drug resistant organism associated with investigational FMT. Any correspondence with medical clinics, institutions, or researchers that are linked to these adverse events, such as where the trial(s) was conducted." Your request was received in the Center for Biologics Evaluation and Research on July 18, 2019.

Beth Brockner-Ryan called the phone number provided in your request on August 26, 2019 and September 9, 2019 and left messages for you with the receptionist, however she has not received a return call from you. Ms. Brockner-Ryan had tried to contact you to ask if you are interested in receiving MedWatch reports involving fecal microbiota transplantations; and to let you know that some of these MedWatch reports had been previously released under FOIA and could be provided to you quickly. In the absence of any contact from you, but in an effort to be responsive, we are enclosing those records. *Please note that you may also receive a response from another part of the Agency.*

This data derives from a passive safety surveillance system (FDA Adverse Event Reporting System (FAERS)) in which adverse events are spontaneously reported to FDA by manufacturers, healthcare providers, patients and others. The reports have not been medically confirmed and therefore cannot be validated by FDA. Additionally, FAERS data do not imply causality. Under reporting is known to occur and duplicate reports may also occur in the database. Please also note that the date the report was received by FDA, may differ from the date of the reported event.

We have withheld portions of pages under Exemption (b)(4), 5 U.S.C. § 522(b)(4). That exemption permits the withholding of trade secrets and commercial or financial information that was obtained from a person outside the government and that is privileged or confidential. The withholding of such information is permitted if disclosure is likely to cause substantial competitive harm to the person who submitted the information.

In addition, we have withheld portions of pages under Exemption (b)(6), 5 U.S.C. § 522(b)(6). That exemption protects information from disclosure when its release would cause a clearly unwarranted invasion of personal privacy. FOIA Exemption 6 is available to protect information in personnel or medical files and similar files. This requires a balancing of the public's right to disclosure against the individual's right to privacy.

You have the right to appeal this determination. By filing an appeal, you preserve your rights under FOIA and give the agency a chance to review and reconsider your request and the agency's decision.

Your appeal must be mailed within 90 days from the date of this response to:

Deputy Agency Chief FOIA Officer
U.S. Department of Health and Human Services
Office of the Assistant Secretary for Public Affairs
Room 729H
200 Independence Avenue, S.W.
Washington, DC 20201
Email: FOIARequest@PSC.hhs.gov

Please clearly mark both the envelope and your letter or email "**FDA** Freedom of Information Act Appeal."

If you would like to discuss our response before filing an appeal to attempt to resolve your dispute without going through the appeals process, please contact:

Beth Brockner-Ryan, Branch Chief
Center for Biologics Evaluation and Research (CBER)
Access Litigation and Freedom of Information Branch
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Building 71, Room 1114
Silver Spring, MD 20993-0002
Email:beth.brocknerryan@fda.hhs.gov
Main Line 240-402-7800
FOI Line 240-402-8008

You also have the right to contact:

FDA FOIA Public Liaison
Office of the Executive Secretariat
5630 Fishers Lane
Room-1050
Rockville, MD 20857
Email: FDAFOIA@fda.hhs.gov

If you are unable to resolve your FOIA dispute through our FOIA Public Liaison, the Office of Government Information Services (OGIS), the Federal FOIA Ombudsman's office, offers mediation services to help resolve disputes between FOIA requesters and Federal agencies. The contact information for OGIS is:

Office of Government Information Services
National Archives and Records Administration
8601 Adelphi Road–OGIS
College Park, MD 20740-6001
Telephone: 202-741-5770
Toll-Free: 1-877-684-6448
Fax: 202-741-5769
E-mail: ogis@nara.gov

If you have any questions or if we can be of further assistance, please let us know by referencing the above file number. You can contact Catherine Wilusz by phone at 240-402-8184 or by e-mail at Catherine.wilusz@fda.hhs.gov.

Sincerely,

Beth A. Brockner Ryan -S

Digitally signed by Beth A. Brockner Ryan -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300052489, cn=Beth A. Brockner Ryan -S
Date: 2019.09.24 09:11:02 -04'00'

Beth Brockner Ryan
Chief, Access Litigation and Freedom of Information Branch

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